Appl. No.

10/657,061

Filed

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September 5, 2003

REMARKS

Upon entry of the foregoing amendment, Claims 1-51, and 62-71 remain pending. Claims 12-43 have been withdrawn. Claims 52-61 have been canceled without prejudice to their further prosecution in a continuation application. New Claims 62-71 have been added.

Objection to Claims 52-61 Under 37 CFR § 1.75

Claims 52-61 stand objected to under 37 C.F.R. § 1.75 as being a substantial duplicate of Claims 1-10. Applicants have canceled Claims 52-61 without prejudice to their continued prosecution in a continuation application. Accordingly, Applicants respectfully request that this objection be withdrawn.

Objections to the Drawings

The drawings stand objected to for failure to comply with 37 C.F.R. § 1.121(d) and for being informal and unclear. Applicants submitted Formal Drawings in a separate communication, dated March 1, 2005. Accordingly, Applicants respectfully request that this objection be withdrawn.

Rejection of the Claims Under 35 U.S.C. § 112

Claims 1, 11 and 52 stand rejected under 35 U.S.C. § 112, ¶ 2, as being indefinite for failing to particularly point out and distinctly claim the subject matter Applicants regard as the invention. Specifically, with regard to Claims 1 and 11, the Examiner states that the phrase "having a DK value of at least 30" is unclear because there are no units of measure for the value of DK.

Applicants have amended Claims 1, 6, 11 and 47 to include the units " $x10^{-11}$ (cm²/sec) (mL O₂)/ (mL x mm Hg)" (the commonly accepted units for DK coefficients). Accordingly, Applicants respectfully request the withdrawal of this rejection. Applicants have canceled Claims 52 rendering the rejection of Claim 52 moot.

Rejection of the Claims under 35 U.S.C. § 103

Claims 1-7, 9-11, 44-48, 50-58, and 60-61 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Sohnges (GB 1 417 650) in view of Ingenito et al. (US 5,986,001). Claims 8, 49, and 59 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Sohnges and Ingenito et al., and further in view of Graham (US 4,166,255). Applicants respectfully traverse these rejections.

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Applicants respectfully submit that the invention, as recited in the claims, is nonobvious in view of Sohnges and Ingenito et al. Modification of the hybrid contact lens disclosed by Sohnges using the material of Ingenito et al. would fail to produce the claimed invention.

Submitted herewith are the declarations of Dr. James Boucher, Dr. William Meyers, Dr. Joseph Barr, and Dr. Jerome Legerton, who together have over a century of experience in the contact lens and cornea fields. All agree that one of ordinary skill in the art would not combine Sohnges and Ingenito to result in the present invention.

Sohnges does not disclose a hybrid contact lens having a hard central portion with a DK of at least 30×10^{-11} (cm²/sec) (mL O₂)/ (mL x mm Hg). "In fact, this patent does not even disclose an oxygen permeable rigid lens material. To the contrary, it discloses attempting to deliver oxygen to the eye through tear pumping or movement under the lens." Legerton Declaration, Paragraph 10; Barr Declaration, Paragraph 10, Boucher Declaration, Paragraph 12; Meyers Declaration, Paragraph 10.

Additionally, Sohnges teaches away from using a hydrophilic skirt and the materials identified in Sohnges are not hydrophilic. See Sohnges, page 1, lines 49-53. Indeed, "there is no disclosure or suggestion in Sohnges to 1) provide a hybrid contact lens with a high DK central portion, 2) provide a hydrophilic skirt, or 3) bonding a high DK central portion to a hydrophilic skirt in any manner." Legerton Declaration, Paragraph 10; Barr Declaration, Paragraph 10, Boucher Declaration, Paragraph 12; Meyers Declaration, Paragraph 10. Applicants have amended Claims 1 and 11 to recite a "substantially flexible hydrophilic portion coupled to the substantially rigid portion at a junction."

Ingenito discloses a lens that "uses an interpenetrating network of preformed uncrosslinked polymers. This combination results in a flexible material which is incompatible with the function of the rigid center in a hybrid contact lens. In addition, the uncrosslinked polymers disclosed in Ingenito could not be used as the soft peripheral skirt in a hybrid contact lens. The Ingenito lens is formed through softening and compressing the polymer mixture. There is no bonding occurring. Further, there is no suggestion to bond the material of Ingenito with any other material, let alone that disclosed in Sohnges." Legerton Declaration, Paragraph 11; Barr Declaration, Paragraph 11, Boucher Declaration, Paragraph 13; Meyers Declaration, Paragraph 11.

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Additionally, there has been a long felt but unsolved need for a hybrid contact lens having a substantially rigid portion with a DK greater than $30x10^{-11}$ (cm²/sec) (mL O₂)/ (mL x mm Hg), and a substantially flexible hydrophilic portion coupled to the substantially rigid portion. See Legerton Declaration, Paragraph 13; Barr Declaration, Paragraph 13, Boucher Declaration, Paragraph 15; Meyers Declaration, Paragraph 13.

In view of the foregoing, Applicants respectfully submit that Claims 1 and 11 are patentable over Sohnges in combination with Ingenito et al. Claims 2-10 and 44-51 depend from Claims 1 and 11, respectfully. Accordingly, Applicants respectfully submit that Claims 2-10 and 44-51 are also patentable over Sohnges in combination with Ingenito et al., not only because they depend from an allowable base claim, but also because each of these claims recites a unique combination of features not taught or suggested by the cited art.

As noted above, Claims 8, 49 and 59 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Sohnges and Ingenito et al., and further in view of Graham. Claim 59 has been canceled without prejudice to its further prosecution in a continuation application, rendering the rejection of Claim 59 moot. Claims 8 and 49 depend from independent Claims 1 and 11, respectively. As discussed above, Applicants respectfully submit that Claims 1 and 11 are patentable over Sohnges in combination with Ingenito et al. Accordingly, Applicants respectfully submit that dependent Claims 8 and 49 are likewise patentable over Sohnges in combination with Ingenito et al. and further in view of Graham, not only because each depends from an allowable base claim, but also because each of these claims recites a unique combination of features not taught or suggested by the cited art.

Applicants have added new independent Claim 62 and new dependent Claims 63-71. Claim 62 recites a hybrid contact lens comprising a substantially rigid portion having a gas permeability value of at least 30×10^{-11} (cm²/sec) (mL O₂)/ (mL x mm Hg) and a substantially flexible hydrophilic portion coupled to the substantially rigid portion. In view of the discussion above, Applicants respectfully submit that Claim 62 is patentable over Sohnges in combination with Ingenito et al. Claims 63-71 depend from Claim 62. Accordingly, Applicants respectfully submit that Claims 63-71 are also patentable over Sohnges in combination with Ingenito et al., not only because they depend from an allowable base claim, but also because each of these claims recites a unique combination of features not taught or suggested by the cited art.

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CONCLUSION

The undersigned has made a good faith effort to respond to all of the rejections in the case and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is respectfully requested to call Applicant's attorney, in order to resolve such issue promptly.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: June 7, 2005

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